510(k) Summary of Safety and Effectiveness
Smith & Nephew RF Cannulae

K090955

Submitted By:	Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116
Date:	April 03, 2009
Contact Person:	Mason W. Robbins, RPCV Regulatory Affairs Specialist Tel: (901) 399-6021 Fax: (901) 399-1557
Proprietary Name:	Smith & Nephew RF Cannulae
Common Name: **Classification Name and Reference:**	Probe, Radiofrequency Lesion 21 CFR 882.4725, Radiofrequency lesion probe
Device Product Code and Panel Code:	GXI / Neurology / 84

JUL 16 2009

Device Description:
Smith & Nephew RF Cannulae are intended to facilitate the placement of Smith & Nephew RF Denervation Probes for the use in RF heat lesion procedures. The RF Cannulae are offered in a variety of lengths, gauges and tip configurations to accommodate various anatomical locations and differences in patient anatomy.

Intended Use:
Smith & Nephew RF Cannulae are intended to facilitate placement of Smith & Nephew RF Denervation Probes. The Smith & Nephew RF Cannulae are indicated for use in RF heat lesion procedures for the relief of pain.

Technological Characteristics:
The proposed Smith & Nephew RF Cannulae are technologically similar to the predicate Smith & Nephew RF Cannulae previously cleared under K063467. Several design modifications were made to the proposed RF Cannulae including changes to improve cannula insertion performance.

Substantial Equivalence Information:
The proposed RF Cannulae are substantially equivalent to the predicate device listed below based on similarities in design features, overall indications for use and material composition.

- Smithy & Nephew RF Cannulae (K063467)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2009

Smith & Nephew, Inc.
c/o Mason W. Robbins, RPCV
Regulatory Affairs Specialist
1450 Brooks Rd.
Memphis, TN 38116

Re: K090955
Trade/Device Name: Smith & Nephew RF Cannulae (See Enclosed list for Models)
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: II
Product Code: GXI
Dated: June 25, 2009
Received: June 30, 2009

Dear Mr. Robbins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ- 401 DMC
HFZ- 404 510(k) Staff
HFZ- 460 (DONED - Marsha L. Burke Nicholas)
D.O.

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Drafted: Marsha L. Burke Nicholas, July 7, 2009
Edited: Marisol Lendor, July 7, 2009
Final: Marisol Lendor, July 7, 2009
Typed: Marisol Lendor, July 7, 2009

IMAGE COPY

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
460	ULMER	7/13/09						
460	Callaway	7/15/09						

Enclosure 1

Smith & Nephew RF Cannulae Models

Catalogue Number	Description
	22 Gauge RF Cannula
7210273	22 gauge, 5cm, 4mm sharp, straight tip
72200031	22 gauge, 5cm, 4mm sharp, curved tip
72200032	22 gauge, 10cm, 10mm sharp, curved tip
72200033	22 gauge, 10cm, 10mm sharp, straight tip
	20 Gauge RF Cannula
7210274	20 gauge, 10cm, 10mm blunt, curved tip
7210275	20 gauge, 10cm, 10mm sharp, curved tip
7210276	20 gauge, 10cm, 5mm sharp, straight tip
7210277	20 gauge, 15cm, 10mm blunt, curved tip
7210278	20 gauge, 15cm, 10mm sharp, curved tip
7210279	20 gauge, 15cm, 5mm sharp, straight tip
	18 Gauge RF Cannula
72200805	18 Gauge, 10cm, 10 mm sharp, curved tip
72200806	18 Gauge, 15cm, 10 mm sharp, curved tip

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K090955

Device Name: Smith & Nephew RF Cannulae

Indications for Use:

Smith & Nephew RF Cannulae are intended to facilitate placement of Smith & Nephew RF Denervation Probes. The Smith & Nephew RF Cannulae are indicated for use in RF heat lesion procedures for the relief of pain.

Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MLB Nicholas

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K090955